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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/902,966	07/12/2001	Waheed N. Khan	X-9340	9239
7590 10/19/2006			EXAMINER	
GIPPLE & HALE			NGUYEN, BAO THUY L	
P.O. BOX 40513 WASHINGTON, DC 20016			ART UNIT	PAPER NUMBER
			1641	

Please find below and/or attached an Office communication concerning this application or proceeding.

U.S. Patent and Trademark Office PTOL-326 (Rev. 08-06)

Paper No(s)/Mail Date _

6) Other:

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I, claims 1-11 and 20 in the reply filed on 25 February 2003 is acknowledged.

Claims 12-19 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Drawings

2. New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application. Applicant is advised to employ the services of a competent patent draftsperson outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 3-6, 8-9 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Nason (US 5,078,968).

Nason discloses a testing unit comprising a collecting swab member disposed inside a housing member having one ore more reagents other test fluid encased therein. At least one filter member are incorporated into the test unit for filtering the reagent and/or the specimen as required for a selected test. Nason discloses a variety of modifications and improvements including having a porous filter member formed simultaneously and integrally with the housing and impregnated with a selected reagent. Test results can be read directly by observing colorimetric changes. See column 10, lines 1-30. It can clearly be seen that the kit of Nason is of a size that can be easily carried in a pocket of a shirt.

5. Claims 1, 2-9, 11 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Schramm et al (US 5,935,864).

Schramm discloses a self-contained analyzing kit for testing body fluid. The kit comprises a sample container having an open capillary end and an open top with a chamber disposed there between, said chamber including means therein for analytical testing; and a vial having a sealed top end, said top end being of preselected size to receive the lower end of the sample container in an air tight arrangement. See column

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- 2, lines 16-41. Schramm also teaches that the chamber accommodates a test strip for analysis of the body fluid. See column 3, lines 60-61. It can clearly be seen that the kit taught by Schramm is of a size that can be easily carried in a pocket of a shirt.
- 6. Claims 1-3, 5-9, 11 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Carpenter (US 6,893,880).

Carpenter discloses a device comprising a sampler and a detection chamber. The sampler is made of an absorbent wick or tubing and a reagent delivery system. The wick or tubing is enclosed in a housing made of a rigid non-water permeable material. The detection member comprising a housing having a test strip carrying appropriate reagents for an assay. Carpenter teaches a mechanism capable of puncturing skin to draw blood or other fluids in the form of a retractable sharp. See column 8, line 25-41. It can clearly be seen that the device taught by Carpenter is of a size that can be easily carried in a pocket of a shirt. Even though Carpenter does not specifically disclose a kit, the device of Carpenter anticipates the instant claims because the kit of claim 1 is nothing more than a housing having a sample collector and a test strip with reagents disposed thereon. Such a device is clearly taught by Carpenter.

7. Claims 1, 2, 5 and 8-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Moisson (US 4,959,196).

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Moisson discloses a device for sampling and analyzing blood comprising an auto-pricker, and a magazine for test strips. These strips comprise a thin support made of flexible plastic on which a reagent is disposed forming a reactive area. The magazine and the auto-pricker forming an integral unit that is a substantially cylindrical elongate form so that the device can be easily stowed away in a pocket like a pen. The device may also be provided with a clip allowing the device to be hooked inside a pocket. See column 2, lines 35-61.

Double Patenting

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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9. Claims 1-11 and 20 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8 of copending Application No. 11/095,133. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are both claiming a kit comprising test strips, an instrument for extracting testing material from a human body, reagents for the test all disposed in an elongated, tubular enclosure.

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

- **10.** No claim is allowed.
- 11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (571) 272-0824. The examiner can normally be reached on Tuesday and Wednesday from 8:00 a.m. -4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Bao-Thuy L. Nguyen

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